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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,016	03/05/2001	Dean K. Pettit	3253	5188

500 7590 05/12/2004

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EXAMINER	
SPECTOR, LORRAINE	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/800,016	PETTIT ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-22* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-13 and 16-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7, 9-22* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Part III: Detailed Office Action

The request filed on 3/1/2004 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/800016 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-7 and 9-22 are pending and under consideration.

Claims 14 and 15 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the paper filed 8/15/2003.

The rejection of claim 19 under 35 U.S.C. §112, second paragraph is withdrawn in view of applicants amendments.

Formal Matters:

The new title of the invention is acknowledged.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9 and 16-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the LEUKINE® Sargramostim product insert, cited by applicants in paper number 5, in view of Chalmers, Manufacturing Chemist & Aerosol News (March 1978, cited by applicants) , and U.S. Patent Number 5,217,954 (Foster et al.), and in the case of claims 4-8, further in view of U.S. Patent Number 5,545,536 (Kaushansky et al.) for reasons of record in the Office Action mailed 5/15/03 at pages 4-6.

Applicants traversal in the paper filed 3/1/2004 has been fully considered but is not deemed persuasive. Applicants argue that the LEUKINE insert indicates that the cytokine can be prepared in lyophilized form without benzyl alcohol, such that there would be no motivation to substitute EDTA for benzyl alcohol. This argument has been fully considered but is not deemed persuasive because the person of ordinary skill in the art would have been motivated to make a shelf-stable *solution* of GM-CSF, as it is well recognized in the art as advantageous to have such, as compared to a lyophilized formulation which must be reconstituted immediately prior to use, such as less chance of dosage error due to incorrect dilution, and easier and quicker administration due to not needing to stop and reconstitute the drug. As stated in the rejection, one of ordinary skill in the art would have been motivated to make the substitution in order to produce a stable composition that could be administered to neonates, as the Sargramostim insert specifically warns against administering benzyl alcohol to neonates. Further, Foster et al. teach specifically the use of EDTA to stabilize a cytokine preparation and protect against degradation. As stated in the previous Office Action, as the person of ordinary skill in the art reading the cited references would have expected GM-CSF stored in the presence of EDTA to more stable than that without. It would not have been necessary for that person of skill in the art to have fully characterized the nature of the degradation observed by applicants in order to be motivated to make the claimed compositions, nor to expect success at doing so.

At pages 8-9, applicants argue that EDTA would not be an obvious choice, and that there is "no evidence in the art that EDTA meets" regulatory guidelines to be used as a preservative. This argument has been fully considered but is not deemed persuasive because applicants argument ignores the teachings of Foster et al., in which EDTA was used to stabilize a pharmaceutical composition of a cytokine. Applicants argument regarding regulatory guidelines

is not persuasive because (a) EDTA is disclosed at the FDA website as an approved drug additive for use in solution (see http://www.accessdata.fda.gov/scripts/cder/iig/getiigWEB.cfm), and (b) applicants have provided *no facts or evidence* to the contrary.

At the bottom of page 9, applicants argue that it would have been "unexpected" that EDTA would specifically reduce N-terminal degradation of GM-CSF. This argument has been fully considered but is not deemed persuasive because EDTA was well known in the art to be a metalloprotease inhibitor, and it would have been obvious to use such to stabilize a cytokine composition such as one comprising Sargramostim. Applicants determination of *how* this might be effected, namely inhibition of N-terminal degradation, is merely characterization of how the effect occurs. It has long been held that "Mere recitation of newly discovered function or property, inherently possessed by things in prior art, does not cause claim drawn to those things to distinguish over prior art" ; see *in re Swinehart and Sfiligoj*, 169 USPQ 226. It remains that it would have been obvious to use EDTA to stabilize a Sargramostim composition in view of its known and expected properties, that is, the expectation that it would stabilize the composition, that is, protect the protein from degradation, in view of its known properties as a metalloprotease inhibitor. It is noted that preventing metalloprotease activity falls within the definition of acting as a preservative, as it would preserve the presence of active protein.

It is noted that applicants remarks at page 9 end with an incomplete sentence.

Claims 10-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the LEUKINE® Sargramostim product insert, cited by applicants in paper number 5, in view of Chalmers, Manufacturing Chemist & Aerosol News (March 1978, cited by applicants) , and U.S. Patent Number 5,217,954 (Foster et al.), as cited in the rejection of claims 1-9 above, and further in view of U.S. Patent Number 6,500,418 B1 (Dieckgraefe et al.) .) for reasons of record in the previous Office Action, mailed 5/15/03, at page 6.

Applicants arguments have been fully considered but are not deemed persuasive for reasons cited above.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent Numbers 5,518,912 and 5,441,882 are cited to demonstrate that EDTA was well known in the art to be a metalloprotease inhibitor at the time the invention was made.

Advisory Information:

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M. ***Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.***

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz. ***Effective 1/21/2004, Dr. Kunz' telephone number is 571-272-0887.***

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner